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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,254	07/31/2001	Daniel K. Recinella	ANGIO P-15 - (500622.2000)	3169
7590	07/19/2004		EXAMINER	
Lloyd McAulay, Esq. Reed Smith LLP 375 Park Avenue New York, NY 10152			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
				3763

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

05

Office Action Summary	Application No.	Applicant(s)	
	09/919,254	RECINELLA ET AL.	
	Examiner	Art Unit	
	Kevin C. Sirmons	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 April 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 24 and 26-48 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 35-43 is/are allowed.
- 6) Claim(s) 24,26,44-46 and 48 is/are rejected.
- 7) Claim(s) 27-34 and 47 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 26, 44-46 and 48 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Teirstein U.S. Pat. No. 5,533,978.

Teirstein discloses a method for supplying a contrast medium to a patient's vascular system comprising: providing a flexible bag filled with contrast medium at essentially atmospheric pressure (14); operatively connecting said flexible bag to the patient's vascular system (fig. 2) via a gas transfer system (10), said gas transfer system including: a dual check valve (16) adapted to be connected to a lower pressure source of contrast medium (fully capable of being adapted (see 20 connect to 14), said dual check valve having a first inlet port (top portion/input end of 42), a first outlet port (distal end/out end of 48) and a first inlet-outlet port (dual check valve portion of 16 connected to syringe (50)), said dual check valve containing a first one-way valve (42) at said first inlet port automatically responsive to the relatively low pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow (col. 5, lines 1-19), said dual check valve containing a second one-way valve (48) at said first outlet port (distal portion of 48) automatically responsive to the relatively high pressure at said first inlet-outlet port to permit downstream fluid flow and to prevent upstream fluid flow

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(48), said first inlet-outlet port in communication with said first and second one-way valves and adapted to be connected to a pump (fig. 2), and a connecting tubular member (22) having an upstream and downstream end, said upstream end in communication with said first outlet port of said dual check valve; purging said gas transfer system of air (col. 5, lines 5-9) delivering said contrast medium from said flexible bag through said gas transfer system to the patient's vascular system (fig. 2), the delivering step including: suction at said first inlet-outlet port by the pump to cause said first one-way valve to automatically open (col. 7, lines 1-11), allowing flow of contrast medium from said bag into the pump (col. 7, lines 1-11), and to cause said second one-way valve to automatically close (col. 7, lines 1-11), preventing fluid flow upstream from said connecting tubular member into the pump, and exerting positive pressure at said first inlet-outlet port from the pump to cause said second one-way valve to automatically open, allowing fluid flow from said pump into said tubular member, and to cause said first one-way to automatically close, preventing upstream fluid flow to the source (col. 7, lines 7-11). However, it may not be clear to one of ordinary skill in the art that the valves disclosed by Teirstein could be automatically responsive to low and high pressures. It is nevertheless, the examiner's position that the valves of Teirstein are automatically responsive to low and high pressures (col. 4, lines 65-67 and col. 7, lines 11-13). In the aforementioned passages, Teirstein clearly teaches that his valves can be check valves, which are identical to the valves disclosed by applicant and that the valves can be ball valves. Both are well known in the art as being automatically responsive to various pressures. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Teirstein to have automatically responsive valves as taught by Teirstein (col. 4, lines 65-67 and col. 7, lines 11-13) to control the flow of

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contrast medium (col. 4, lines 65-67); as to claim 26, (56); as to claim 44, (col. 6, lines 59-67 and col. 7, 1-17); as to claim 45, (see above rejection and a tubular member having an upstream end connected to the outlet port and a down stream end connectable to a catheter (col. 4, lines 53-54); as to claim 46, (col. 4, lines 53-54 and col. 7, lines 16-17); and as to claim 48, (see above rejections).

Allowable Subject Matter

Claims 27-34 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 35-43 are allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record disclose the device substantially as claimed at the time the invention was made except for a third one-way valve in communication with said downstream end of the tubular member to permit downstream fluid flow from the tubular member and to prevent upstream fluid flow in said tubular member.

Response to Amendment

Drawings

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: The gas transfer system mentioned in the specification does not have a reference numeral.

Applicant's proposed drawing correction, corrected drawings, and/or amendment to the specification to add the reference sign(s) in the description, are acceptable. Therefore, the objection has been withdrawn.

Response to Arguments

Applicant's arguments with respect to claims 24 and 26-48 have been considered but are moot in view of the new ground(s) of rejection.

Basically, Teirstein discloses various types of valves including, manual valves check valves and ball valves, which can all be used in his invention at the users discretion. It is well known in the art that check and ball valves work automatically as clearly disclosed in applicant's specification. That is clearly why applicant uses check valves.

Applicant has taken the word typically to mean that the manifold would always have extra valves. However, typically does not mean always and could include sometimes, occasionally or not at all. Therefore, it may not be necessary to have extra valves 44 and 46. Additionally, even if the valves were present at the time, Teirstein did not indicate that they were in use. Therefore, there would be no fluid flow from in connection to the valves, which would contaminate the closed system of Teirstein. Accordingly, Teirstein disclosed the claimed invention.

Moreover, Teirstein clearly discloses the drawing step which includes "to cause said first one-way valve to automatically open (see above rejection), allowing flow of contrast medium from said bag into the pump, and to cause said second one-way valve to automatically close,

preventing fluid flow upstream from said connecting tubular member into the pump" and vice versa (see above rejection; emphasis added).

As to applicant response that the Examiner on page 4 and 5 (response to arguments) appears to suggest that such a precise interaction between the two valves is well known, it is the examiner's position that the valves are well known and that Teirstein teaches using the valves as disclosed by applicant. Furthermore, applicant and Teirstein valves are structurally identical since applicant has not given any structure to his valve and there is no reason why the valves of Teirstein would not perform the same as applicant's valves. The evidence to support the examiner's rational is clearly supported in Teirstein and the fact the applicant again (emphasis added) uses the same valve as Teirstein. There is no evidence in Teirstein that would indicate that the valves would not perform like the valves of applicant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

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In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

Kevin C. Sirmons

Kevin C. Sirmons

Patent Examiner

7/7/04